Emtricitabine/tenofovir disoproxil fumarate   WHOPAR part 5   April 2020
200 mg/300 mg tablets
(Macleods Pharmaceuticals Ltd), HA561

LABELLING

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PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton label (blister and HDPE bottle)

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1. NAME OF THE MEDICINAL PRODUCT

[HA561 trade name]*

2. STATEMENT OF ACTIVE SUBSTANCE

Each film-coated tablet contains 200 mg emtricitabine and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

3. LIST OF EXCIPIENTS

Contains lactose.
See the patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

HDPE bottle: 30 film-coated tablets

Alu-Alu blister: 10x10 film-coated tablets

5. METHOD AND ROUTE OF ADMINISTRATION

Oral use.
Read the patient information leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

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* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

HDPE bottles   :   Store below 30°C, in a dry place protected from light.
Alu-Alu blisters: Store below 25°C, in a dry place protected from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE SUPPLIER

Macleods Pharmaceuticals Limited
304, Atlanta Arcade
Marol Church Road
Andheri (East)
Mumbai – 400 059, India
Tel: +91-22-66762800
          +91-22-6113 2900
Fax: +91 -22-28216599

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

HA561

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

[HA561 trade name]

2. NAME OF THE SUPPLIER

Macleods Pharmaceuticals Ltd

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch No> or <Lot> or <BN> {number}